510(K) SUMMARY

SIALOTECH DILATION BALLOON KIT AND ACCESSORIES

510(k) Number K072334

JUL 18 2008

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Date Prepared: August 2007

Trade Name: Sialo Drain

Classification Name: CFR Classification section 878.4200 (Product code OAJ)

Classification: Class II medical Device

Predicate Device: The Sialo Drain device is comparable to the following predicate devices:

- The Tal MicroDrainage Set manufactured by Boston Scientific Corp. (510k exempt).
- The Drainage Catheters manufactured by Cook Inc. (510k exempt)
- The Jacobs Frontal Sinus Cannula manufactured by Hood Laboratories (510k exempt).
- The Jackson Lachrymal Intubation Set manufactured by Accutome (510k exempt).

- The Lachrymal Jones Tube manufactured by Gunther Weiss Scientific Glassblowing co. (510k exempt).

Device Description: The Sialo drain is a flexible, single lumen, sterile, single use, disposable cannula made of biocompatible radio-opaque polyurethane material.

Intended Use / Indication for Use:

The Sialo Drain is a medical device for use by qualified surgeons in the treatment of salivary gland diseases for the purpose of drainage.
The Sialo Drain is an intraoral/extraoral drainage catheter, intended to allow continuous drainage of saliva and/or fluid irrigation of the salivary duct by temporary insertion into the salivary gland, whether orally or through the cheek.

Performance Standards: None.

Test Data: The Sialo Drain device has been subjected to extensive safety, performance, and validation testing before release. Final testing of the SialoTech device included various performance tests designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

Substantial Equivalence: The Sialo Drain device is similar to other drains which are put in many body orifices and wounds after surgical procedures, similar to the Sialo Drain.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices, is that the Sialo Drain device is substantially equivalent in safety and efficacy to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sialo Technologies, Ltd.
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20 Hata'as St, 44425 Kfar Saba ISRAEL

JUL 18 2008

Re: K072334
Trade/Device Name: Sialo Drain
Regulation Number: 21 CFR 878.4200
~~Regulation Name: Introduction/drainage catheter and accessories~~
Regulatory Class: I
Product Code: OAJ
Dated: June 30, 2008
Received: July 2, 2008

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K072334

Device Name: **Sialo Drain**

Intended Use Statement:

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Prescription Use __√___ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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